IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-JLH
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

FERRING'S REPLY BRIEF IN SUPPORT OF
ITS MOTION FOR JUDGMENT AS A MATTER OF LAW

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I. CLAIM 7 OF THE UMN PATENT IS INVALID FOR LACKING WRITTEN DESCRIPTION

A. Inventor testimony cannot substitute for written description

The test for written description "requires an objective inquiry into the four corners of the specification from the perspective of a [POSA]." *Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010). Finch/UMN suggest "[t]he specification ***explicitly*** discloses the claim elements," D.I. 514 at 7 (emphasis in original), but any reference in the specification comes only within a "laundry list" of compositions that may or may not satisfy the claims, which is insufficient, *Lipocine Inc. v. Clarus Therapeutics, Inc*., 541 F. Supp. 3d 435, 446 (D. Del. 2021). The Federal Circuit has "expressly rejected the argument that the written description requirement is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc*., 923 F.3d 1368, 1380 (Fed. Cir. 2019) (cleaned up). For the Markush group limitation, the specification names the ten classes of bacteria included in claim 7 but suggests that compositions containing any number of them—from a single class to all ten—may be embodiments. JTX-1 at 5:25-29, 7:67-8:4. The specification does not explain or suggest the criticality of any of the claimed class(es) or claimed number of classes (6 of 10). Similarly, with respect to the relative abundance limitation, the specification discusses decreasing Proteobacteria only in general terms and does not link satisfaction of the Markush group limitation to achieving the relative abundance limitation, as required by the claim. See JTX-1 at 15:42-52.

Seemingly recognizing these deficiencies in the specification's disclosure, Finch/UMN rely on inventor testimony to try to bridge the gap. But "inventor testimony cannot establish written description support where none exists in the four corners of the specification." *Nuvo Pharms,* 923 F.3d at 1381. Thus, Finch/UMN's reliance on Drs. Khoruts's and Sadowsky's testimony cannot satisfy the written description requirement, not least because their testimony is

the type of "conclusory and circular 'because I said so' testimony" that courts have found insufficient to survive JMOL in other contexts. *NexStep, Inc. v. Comcast Cable Commc'ns*, *LLC*, 119 F.4th 1355, 1374 (Fed. Cir. 2024).

Additionally, while "***in some circumstances***, a patentee may rely on information that is '***well-known in the art***' for purposes of meeting the written description requirement," *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011), such circumstances do not exist here. There is no evidence in the trial record that it was "well-known in the art" ***at the time of the invention*** that using the specific manufacturing method described in the UMN patent (which is not required in claim 7) to prepare a sample from a healthy donor (which also is not required) would result in a composition with at least six classes of bacteria commonly found in a healthy gut microbiome (which never was linked to the ten specific classes recited in the claim), and that administering that composition to a patient would necessarily result in at least a 10% reduction in Proteobacteria (which testimony shows does not always occur). *See id.; Carnegie Mellon Univ. v. Hoffman-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008). Finch/UMN also suggest that Drs. Khoruts and Sadowsky testified "on how the disclosures would be read by a POSA." D.I. 514 at 7. However, they testified to their own understanding and experience, not that of a POSA. *Compare* D.I. 514 at 3 *with* Tr. 189:2-14; *compare* D.I. 514 at 3 *with* Tr. 156:18-158:12. And inventors are set apart from a POSA, generally being understood to be persons of extraordinary skill in the art. *See, e.g., Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). Even if Dr. Khoruts or Dr. Sadowsky appreciated these issues at the time of the invention, it is not described in the specification and there is no evidence that such information was "well-known in the art" at the time of the invention. This is fatal to the validity of claim 7.

B. The specification does not show a correlation between the Markush group limitation and the relative abundance limitation

Despite uncontested evidence that claim 7 encompasses at least 210 different compositions (and, if the reality of the gut microbiome is considered, millions of compositions, *see* D.I. 502 at 5-6), Finch/UMN suggest that the breadth and unpredictability of the claimed invention can be set aside because "the UMN specification identifies structural properties of the claimed compositions and clinical outcomes of the patients so treated." D.I. 514 at 6. "Although it is true that functional claim language can meet the written description requirement when there is an established correlation between structure and function, [Finch/UMN] fail to establish any such correlation." *Bos. Sci.*, 647 F.3d at 1366.

Example 1 (including the corresponding figures) cannot provide a correlation between the Markush group limitation and the relative abundance limitation. It is uncontroverted that the composition in Example 1 was manufactured the "old-fashioned way," and that neither the screening process from Example 2 nor the processing steps of Examples 3 and 4 were used. Tr. at 143:25-144:16, 151:15-18, 161:20-23. Finch/UMN attempt to dismiss this as a mere "factual argument about what weight Example 1 should receive," D.I. 514 at 4, but as discussed *infra*, Finch/UMN elsewhere argue the criticality of those steps to the claimed invention. Additionally, Dr. Khoruts's testimony regarding Example 1 confirmed that he could not interpret Figure 1 "[j]ust by looking at the graph," and, even considering the text at column 17, Dr. Khoruts's testimony was limited to noting that the patient sample included more than 40% of Mollicutes ***and*** Proteobacteria before transplantation and was dominated by Firmicutes after. Tr. at 157:13-158:12; *see also* JTX-1 at 17:21-27. This is not sufficient to show a specific reduction in Proteobacteria of at least 10%, and even if it were, it says ***nothing*** about the makeup of the donor sample. Instead, Finch/UMN argue that presentation of the donor sample's makeup in the

stacked bar chart of Figure 1 was "standard," D.I. 514 at 4, but ignore that (i) no witness testified that the donor sample makeup can be ascertained from Figure 1 and (ii) the "standard" presentation of such material also requires a table of data that would show specific values from the stacked bar chart, Tr. at 843:19-844:9, 856:12-857:16, 861:8-18.

Moreover, even if Example 1 provided information correlating the Markush group limitation to the relative abundance limitation, it is undisputed that Example 1 concerns only a single donor/patient and that an N of 1 is not science. D.I. 502 at 11. Finch/UMN suggest that this argument "finds no support in the law," D.I. 514 at 4, but tellingly cite no authority in support. Here, both UMN's own inventor and Ferring's expert agree on what is acceptable from a scientific standpoint (N of 1 is not), Tr. at 155:6-11, 850:8-851:7, and thus a POSA would not consider Example 1 sufficient to demonstrate that the inventors were in possession of the claimed invention. Instead, as stated in the specification more is needed, JTX-1 at 28:31-37, and thus the description simply describes a research plan, which as a matter of law is not sufficient for written description. *Ariad*, 598 F.3d at 1359.

With respect to Example 4, Finch/UMN continuously conflate clinical outcomes data with taxonomic data and misleadingly suggest that "Ferring's argument that Example 4 lacks 'taxonomic data' is wrong too." D.I. 514 at 4. But UMN's own inventor confirmed that it is "true that the only taxonomic data in [the UMN] patent is for the single patient from Example 1." Tr. at 152:14-16, *see also* Tr. at 842:15-23, 858:7-17. And nowhere in the UMN patent is therapeutic effectiveness (or any other clinical outcome) equated with any specific reduction in levels of Proteobacteria, much less the claimed 10% reduction. Thus, Example 4 does not provide any taxonomic data or information from which taxonomic data could be inferred for either the donor compositions used therein or the patients' before and after results.

C. Claim 7 does not require donor screening or specific processing

Finch/UMN argue that "the specification provides detailed descriptions to ensure the claimed fecal extract includes those 6 classes of bacteria, *e.g.*, via extensively described protocols for (1) donor screening . . . and (2) processing the fecal material." D.I. 514 at 3. As explained above, however, the specification itself references inclusion of 6 of 10 classes of bacteria only as one possibility in laundry lists covering compositions containing from 1 to all 10 of the named classes. Also, Finch/UMN's reliance on the testimony of Dr. Sadowsky to suggest that the Markush group limitation necessarily would be satisfied if those protocols are followed,[1] and on the testimony of Drs. Khoruts and Sadowsky to suggest that achieving clinical benefits after administration would be associated with satisfying the relative abundance limitation, *see* D.I. 514 at 3, cannot show written description for the reasons described in Section I.A. Regardless, claim 7 requires neither donor screening nor specific processing of the fecal material. The full scope of claim 7 covers the administration of any composition containing at least six of the ten classes of bacteria, as long as it results in at least a 10% reduction in the patients levels of Proteobacteria. JTX-1 at cl. 7.

Finally, Finch/UMN's purported responses to Ferring's arguments on inherency, D.I. 514 at 7-9, miss the mark. First, as noted above, Finch/UMN attempt to read a requirement for a "healthy" donor into claim 7's reference to a fecal extract from a donor fails. Claim 7 encompasses the use of material from any donor, not just a healthy donor, and requires the fecal composition contain at least 6 classes of bacteria, not as many classes as could be preserved. JTX-1 at cl. 7. Second, as explained in Ferring's Opening Brief, there is no evidence that using a

[1] Contrary to Finch/UMN's representation, Dr. Treangen confirmed the data on which he was questioned came from an "initial" study involving about 500 individuals. Tr. at 856:1-11. There is no evidence the results were available or "well-known in the art," at the time of the invention.

healthy donor or the processing steps, neither of which are claimed, would result in a composition with at least six ***of the ten specific bacterial classes enumerated in the claim***. D.I. 502 at 8. Additionally, Finch/UMN's representation that using "the claimed method" will "transfer[] '***all***' of the classes," D.I. 514 at 7-8 (emphasis in original), is belied by the fact that the claim does not require using any specific processing steps. Third, the inventors never tied "capable of passing through a 0.5 mm sieve" to the "retention of bacterial classes" or preserving bacterial diversity, as suggested by Finch/UMN. *Compare* D.I. 514 at 8 *with* Tr. at 97:25-99:16, 189:24-192:13. Fourth, the full breadth of the claim encompasses ***any*** combination of at least six of the ten listed classes, and thus, the specification must support the grant of such a broad claim. Regardless, there is no data in the UMN patent showing what classes were present in the donor samples provided to the patients in Example 4. Fifth, as described in Section I.B, the UMN patent does not tie the relative abundance limitation to a therapeutic effect. Finally, as discussed in Section I.A, there is no evidence of record that information concerning the Markush group or relative abundance limitations was "well-known in the art" at the time of the invention.

For the above reasons, the trial evidence shows that claim 7 of the UMN patent is invalid for lack of written description and JMOL is proper here.

II. JMOL OF NO INFRINGEMENT OF CLAIM 7 OF THE UMN PATENT IS WARRANTED

A. No induced infringement

The testimony that Finch/UMN adduced at trial with respect to specific intent was limited to a singular argument—that Ferring instructs healthcare providers to treat CDI. *See* Tr. at 321:11-328:9, 379:3-13. There was no testimony presented at trial that Ferring has taken active steps to encourage healthcare providers to perform "[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof." Faced with this reality, Finch/UMN respond to a distorted version of Ferring's JMOL arguments.

Finch/UMN now argue for the first time that the preamble of claim 7 is not limiting and frame the issue as an attempt by Ferring at post-verdict claim construction. D.I. 514 at 9-10. However, Finch/UMN have treated the preamble as limiting throughout this litigation. *See, e.g.,* Ex. A at 326-331; Ex. B at ¶ 59; Ex. C at 263. And at trial, Dr. Stollman opined on infringement of the preamble—specifically, one of his three "Summary of Opinions" was "'914 patent, claim 7: Ferring instructs healthcare providers to administer REBYOTA in an effective amount in a patient ***in need thereof***." Ex. D at 5.16. The "in need thereof" language is only in the preamble, *see* JTX-1, cl. 4, and, as such, Dr. Stollman treated the preamble as limiting. *See also* Tr. 328:6-9 and Ex. D at 5.28; Tr. at 359:16-360:4, 378:19-379:2 and Ex. E at 7.22.

Consistent with the parties' treatment of the preamble, Federal Circuit precedent confirms it is limiting. "[C]laim construction analysis of statements of intended purpose in methods of using apparatuses or compositions has tended to result in a conclusion that such preamble language is limiting." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1341 (Fed. Cir. 2021) (collecting cases). This is because "claims to methods of using such . . . compositions are not directed to what the method 'is,' but rather they typically rely entirely on what the method 'does[,]'" which "is usually recited in [the claim's] preamble." *Id.* Here, the preamble recites a method of "decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof," JTX-1, cl. 4, which is "a statement of the intentional purpose for which the method must be performed," *Eli Lilly*, 8 F.4th at 1342. This statement of intentional purpose is reflected in the wherein clause, which states "wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration of said pharmaceutical composition." JTX-1, cl. 4. In addition, the preamble's "in a patient in need thereof" provides antecedent basis for the term "said patient" in the body of the claim—providing further support for the limiting nature of the preamble. JTX-1,

cl. 4; *Eli Lilly*, 8 F.4th at 1343 (finding the preamble limiting where the preamble "provide[s] antecedent basis for at least one later claim term in the independent claim[]").

Because the preamble is limiting, it must be assessed for liability of induced infringement. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc*., 7 F.4th 1320, 1330 (Fed. Cir. 2021) (holding that "substantial evidence in this case supports the jury's determination that Teva's partial label contained information ***encouraging*** each claimed step and ***the preamble***").[2] To show inducement, Finch/UMN must prove specific intent and active steps taken to encourage direct infringement." *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015). Finch/UMN failed to do so here. Finch/UMN do not dispute that the label for REBYOTA is devoid of any mention of relative abundance of Proteobacteria. While Finch/UMN assert that proof of inducement is not limited to the label, D.I. 514 at 12, the evidence they presented at trial was used only to suggest that Ferring instructs HCPs to treat CDI, not that Ferring instructs HCPs to "decreas[e] the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof." *See* Tr. at 321:11-328:9, 379:3-13.

Finch/UMN try to infer specific intent by suggesting that Ferring's advertising and promotion of REBYOTA's use for preventing recurrence of CDI is evidence that REBYOTA causes changes in the microbiome. *See* D.I. 514 at 10-11.While REBYOTA may cause changes in the microbiome, this does not prove specific intent to encourage a method of reducing the relative abundance of Proteobacteria. In fact, as stated in the Prescribing Information, "[t]he mechanism of action of REBYOTA has not been established." PTX-117.8. Moreover, even if Ferring has knowledge that, in some patients, there is a reduction in the relative abundance of

[2] This is in contrast to *Ferring Pharms. Inc. v. Fresenius Kabi USA, LLC,* 645 F. Supp. 3d 335, 379 (D. Del. 2022), D.I. 514 at 12, where the court never considered if the preamble was limiting and thus did not consider whether the ANDA applicant induced infringement of the preamble.

Proteobacteria with the administration of REBYOTA, "[i]t is well-established that 'mere knowledge of possible infringement by others does not amount to inducement.'" *Takeda.,* 785 F.3d at 631. Because Finch/UMN presented no evidence (substantial or otherwise) that Ferring had the specific intent to encourage HCPs to use REBYOTA to perform "[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof," *see GlaxoSmithKline LLC*, 7 F.4th at 1330, JMOL is proper here.

B. No contributory infringement

In an effort to get around Dr. Stollman's conclusory opinion on contributory infringement, Tr. at 327:20-24, Finch/UMN once again conflate the indicated use of REBYOTA with the claimed use, D.I. 514 at 13. However, no evidence was presented that these uses are one and the same. Finch/UMN did not demonstrate that a patient "in need [] of" a decrease in Proteobacteria is necessarily a patient with rCDI. In fact, the UMN patent reflects otherwise. *See, e.g.,* JTX-1 at 14:34-60 (listing other disease states); *see also compare* JTX-1 at cl. 4 (no disease state specified) *with* JTX-1 at cls. 1, 21 (specifying CDI). Moreover, the evidence at trial demonstrated that when REBYOTA was administered to rCDI patients (patients who, according to Dr. Stollman, are in need of a reduction in their relative abundance of Proteobacteria), more than 15% of those patients did not experience the claimed 10% reduction in Proteobacteria. PTX-136.66; Tr. at 359:16-363:4, 506:10-507:1. This is a substantial non-infringing use. *See Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 684 (D. Del. 2016); *Grunenthal GmbH v. Alkem Lab'ys Ltd*., 919 F.3d 1333, 1340-41 (Fed. Cir. 2019). Finch/UMN's efforts to distinguish these cases as "critically different" based on "off-label" use, D.I. 514 at 14-15, again conflate the indicated use with the claimed use. REBYOTA is not indicated to "decrease the relative abundance of Proteobacteria in a patient in need thereof"; instead, it is indicated to

prevent the recurrence of CDI. When administered according to its indication, more than 15% of patients do not practice the claimed use—this is a substantial non-infringing use.

III. JMOL OF NO INFRINGEMENT OF CLAIMS 16 AND 21 OF THE '309 PATENT IS WARRANTED

There is no substantial evidence that REBYOTA "is in an amount effective for ***treating*** recurrence of *C. difficile* infection," JTX-4, cl. 12, such that Ferring infringes claims 16 and 21 of the '309 patent. Finch/UMN first point to statements made during Ferring's opening and closing, as well as testimony from Ferring's testing non-clinical expert, Dr. Johnson, using the words "treatment" and "treat" as evidence that Ferring "conceded" that REBYOTA is a "an FDA-approved safe and effective ***treatment*** for C. diff." D.I. 514 at 22 (citing Tr. at 51:16-24, 807:7-9, and 1248:1-3). But attorney argument statements made during opening and closing are not evidence. Tr. at 24:19-21; D.I. 482 at 3. Moreover, Dr. Johnson confirmed on cross-examination that he was not providing any opinions on the "treatment" limitation in the '309 patent. Tr. at 791:16-793:10; Ex. F at 10.1-10.2.

Finch/UMN completely ignore that both that the specification and prosecution history distinguishes between treatment and prevention. *See* D.I. 502 at 23. Further, Finch/UMN do not dispute that the FDA determined that REBYOTA does not treat CDI, as reflected in the "Limitation of Use" in the REBYOTA Prescribing Information. PTX-117.2 ("REBYOTA is not indicated for treatment of CDI"). This determination was made based on the results of Ferring's clinical trials, as reflected in the Clinical Studies section of the Prescribing Information. PTX-117.9; 21 C.F.R. § 201.57(c)(15). There is no substantial evidence that those findings by the FDA should be supplanted with Ferring's marketing statements and the conclusory opinion of Dr. Stollman, as Finch/UMN argue. *See* D.I. 514 at 23.

IV. JMOL THAT CLAIM 2 OF THE '080 PATENT AND CLAIM 16 OF THE '309 PATENT ARE OBVIOUS IS WARRANTED

A. Claim 2 of the '080 patent

Finch/UMN's claim differentiation argument, D.I. 514 at 18-21, misapprehends Ferring's position—Ferring has not argued that independent claim 1 and dependent claim 2 of the '080 patent have the same scope. Ferring's position is that there is nothing novel in claim 2. *See* D.I. 502 at 17-19. Simply put, claim 1 discloses a "cryoprotectant," and, as Dr. Benson admitted, the purpose of adding a cryoprotectant is to protect against freezing. Tr. at 354:1-4. Further, the jury found that adding an antioxidant to claim 1 was obvious, and again as Dr. Benson admitted, the purpose of adding an antioxidant is to keep oxygen away. *Id*. This mirrors claim 2: "wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is ***frozen*** or ***exposed to air***." JTX-6, cl. 2.

Having chosen not to put on a rebuttal invalidity case and not to move for JMOL on the jury's obviousness finding with respect to dependent claim 9 of the '080 patent, Finch/UMN now resort to a new claim construction argument—that the claimed "enema delivery system" must have some added measure to "protect the fecal bacteria within the composition from destruction when the sealed container is frozen or exposed to air" that is not the addition of a cryoprotectant, the addition of an antioxidant, or being stored in a sealed container. *See* D.I. 514 at 19 (arguing for the first time that the specification differentiates between "potential modifications to the delivery vehicle to render it "substantially or completely oxygen free," and "substances that may be added to the pharmaceutical composition to stabilize the bacteria in the cold and prevent them from being destroyed during storage and transport"). [3] This argument was

[3] In Finch/UMN's Rule 50(a) motion, Finch/UMN admitted that an antioxidant would meet the "when the sealed container is exposed to air" language of claim 2. D.I. 475 at 15.

never presented during claim construction, nor was it argued at trial. This argument is therefore waived. *Enovsys LLC v. Nextel Commc'ns, Inc.*, 614 F.3d 1333, 1345 (Fed. Cir. 2010). Moreover, nothing Finch/UMN cite to in the specification exclude that the claimed cryoprotectant in the enema delivery system would "protect[] the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen" or that adding an antioxidant in the enema delivery system or storing the composition in a sealed container can "protect[] the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is . . . exposed to air." JTX-6, cl. 2. It is common sense that it would, as the unrebutted testimony of Dr. Britton, in fact, demonstrates. Tr. at 882:21-883:12.

Finch/UMN make a second attempt at post-verdict claim construction by arguing that "frozen or exposed to air" means "frozen *and* exposed to air." D.I. 514 at 20-21. Notwithstanding that this argument is also waived because it was not raised at claim construction, *Enovsys*, 614 F.3d at 1345, such a position is inconsistent with Finch/UMN's position at trial, and, if taken as true, would mean Finch/UMN failed to meet their burden of proof of infringement. Specifically, at trial, Dr. Benson testified that REBYOTA met claim 2 solely based on claim 2's "exposed to air" language, not the "frozen" language. Tr. at 391:16-392:9. This further enforces that the claim is written as alternatives, not requiring "both" as Finch/UMN now argue. D.I. 514 at 20-21. *Intel Corp. v. Qualcomm Inc.*, 2023 WL 4196901, at *3-*4 (Fed. Cir. June 27, 2023) is distinguishable as it states that "'or' can refer to alternatives" and that "the Board properly analyzed the phrase in context." *Id.* at *4. Here, Finch/UMN never requested that the Court perform that analysis. Nevertheless, the evidence supports that both "frozen" and "exposed to air" are obvious, and no reasonable juror could have found otherwise.

B. Claim 16 of the '309 patent

Finch/UMN do not dispute that: (i) the only potential novel aspect of claim 16 is that "the

cryoprotectant comprises [PEG];" (ii) according to Finch/UMN's expert Dr. Park, PEG is an antioxidant; (iii) the jury found adding an antioxidant to the claimed enema product was obvious (which Finch/UMN does not attempt to reverse on JMOL); (iv) PEG is a glycol; and (v) Hlavka teaches adding glycol as a cryoprotectant to an enema FMT product. *See* D.I. 502 at 20. Faced with these findings, Finch/UMN argue that "a finding that using any antioxidant is obvious does not mean that a narrower claim directed to using a particular type of antioxidant—PEG—is obvious as well, let alone one directed to its use as a cryoprotectant." D.I. 514 at 16. However, the testimony from Finch/UMN's own expert Dr. Park would lead a reasonable juror to conclude that there are a "finite number" of glycols that are suitable to function as cryoprotectants in pharmaceutical compositions and that a POSA would therefore have "good reason to pursue" PEG given its added benefit as an antioxidant. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 402-03 (2007); Tr. at 341:8-342:20, 343:25-344:4. Finch/UMN's reliance on Ferring's statements to the PTO during prosecution of an entirely different patent family, D.I. 514 at 17 (citing PTX-979.535), is at odds with Dr. Park's testimony, which the jury already credited in finding claim 21 of the '309 patent obvious.

C. There is no substantial evidence of objective indicia of nonobviousness

No substantial evidence ties any objective indicia of nonobviousness to the only possible points of novelty in claim 2 of the '080 patent ("wherein the system protects the fecal bacteria within the pharmaceutical composition from destruction when the sealed container is frozen or exposed to air") and claim 16 of the '309 patent ("wherein the cryoprotectant comprises polyethylene glycol"). ***First***, Rebiotix's recognition of Dr. Borody as a pioneer in the field of FMT, *see* D.I. 514 at 21, has no connection to the purported novel aspects of the claims. ***Second***, there is no evidence that there was a long-felt need for PEG as a cryoprotectant, nor did Finch/UMN provide evidence that additional protection to the "system" from freezing or

exposure to air was needed. In any event, if there was such a need, Hlavka met that need first. Tr. at 1255:22-1256:3. ***Third***, Finch/UMN make no effort to tie the licensing of either the '080 patent or the '309 patent to the supposed novel features, thereby "los[ing] sight of the true purpose of the nexus requirement, which is to consider whether "the fact-finder can infer that the licensing 'arose out of recognition and acceptance of the subject matter claimed' in the patent." *Teva Pharms. Int'l GmbH v. Eli Lilly & Co*., 8 F.4th 1349, 1364 (Fed. Cir. 2021). ***Fourth***, Finch/UMN cannot credibly argue that REBYOTA was a commercial success, much less that any such success is tied to the novel aspects of the remaining claims. For these reasons, no reasonable jury could have found that claim 2 of the '080 patent and claim 16 of the '309 patent would not have been obvious in light of Hlavka and the knowledge of a POSA.

V. THE COURT SHOULD GRANT JMOL OF NO WILLFULNESS

A. The Borody patents

For the first time, Finch/UMN now assert that post-issuance activities support the jury's willfulness verdict on the Borody patents. But their alleged post-issuance evidence is as deficient (if not more so) as their previously alleged pre-issuance conduct. Finch/UMN's new argument relies entirely on evidence that Ferring (i) monitored the patent portfolio assigned to Finch and (ii) launched REBYOTA during this litigation "despite knowing the risk of infringement" and with allegedly weak infringement defenses. D.I. 514 at 24, 26, 28.

On the first point, Finch/UMN's position that routine competitive intelligence justifies a finding of willfulness would turn a standard business practice into evidence of willful infringement. *Contra Amgen, Inc. v. Sanofi*, 2016 WL 393857, at *2 (D. Del. Jan. 29, 2016); *see also HOYA Corp. v. Alcon Inc.*, 713 F. Supp. 3d 291, 317 (N.D. Tex. 2024). And the case on which Finch/UMN rely is factually inapposite. There, willfulness was based not just on monitoring of the plaintiff's products and literature for decades, but also on unrebutted evidence

that (i) the defendant did not employ full-time development staff, (ii) no due diligence occurred during the acquisition, and (iii) defendant created a "culture of copying." *WCM Indus., Inc. v. IPS Corp.*, 721 Fed. App'x 959, 971-72 (Fed. Cir. 2018). That is not the case here.

Further, Ferring's launch of REBYOTA in early 2023 is not evidence of willfulness. D.I. 514 at 26. First, "there is [no] universal rule that to avoid willfulness one must cease manufacture of a product immediately upon learning of a patent, or upon receipt of a patentee's charge of infringement, or upon filing of suit." *Gustafson, Inc. v. Intersys. Indus. Prod., Inc.*, 897 F.2d 508, 511 (Fed. Cir. 1990). And faulting Ferring for not designing around is untethered to the law. *See, e.g.*, *Plastic Omnium Adv. Innovation & Rsch. v. Donghee Am., Inc.*, 387 F. Supp. 3d 404, 421-22 (D. Del. 2018). Finch/UMN point to no evidence that launching REBYOTA demonstrated a subjective intent to infringe and merely handwave at evidence to the contrary. Ferring had a good faith belief it did not infringe the Borody patents. D.I. 501 at 24-28; D.I. 511 at 10-13; *Greatbatch Ltd. v. AVX Corp.*, 2016 WL 7217625, at *4-*5 (D. Del. Dec. 13, 2016); *see also Gustafson*, 897 F.2d at 510-11. That the jury invalidated half of the asserted Borody patent claims shows Ferring's belief was not unfounded, as does Finch/UMN's failure to seek summary judgment. *SiOnyx LLC v. Hamamatsu Photonics K.K.*, 981 F.3d 1339, 1355 (Fed. Cir. 2020).

With respect to pre-issuance conduct, Finch/UMN's assertion that pre-issuance conduct need not be particularly egregious is flawed. While courts have allowed pre-issuance evidence at trial, it is given less weight unless it "demonstrate[s] 'particularly egregious behavior.'" *Sonos, Inc. v. D&M Holdings, Inc.*, 2017 WL 5633204, at *4 (D. Del. Nov. 21, 2017). Moreover, the case law is almost universally consistent in finding pre-issuance activity relevant only where there is direct or circumstantial evidence of copying. *See, e.g.*, *Sonos*, 2017 WL 5633204, at *3-*4 (collecting cases); *see also Bioverativ Inc. v. CSL Behring LLC*, 2020 WL 1332921, at *4 (D. Del. Mar. 23, 2020). Significantly, Finch/UMN have seemingly abandoned their copying

argument on the Borody patents. *Compare* D.I. 514 at 23-27 *with* D.I. 514 at 27-33.

Further, none of the evidence Finch/UMN do cite, even taken as a whole and with inferences in Finch/UMN's favor, can support the jury's finding of willfulness. Specifically, Finch/UMN point to (i) Ferring's knowledge of the Borody patents' parent application, (ii) an alleged interest in the Borody patent application in 2014, but failure to license, (iii) the cost sharing provision of the merger agreement, and (iv) a failure to design around. D.I. 514 at 23-27. But this evidence is insufficient for a reasonable juror to conclude that Ferring had the required subjective intent to infringe. In fact, the only logical conclusion is that Ferring subjectively believed that it would not infringe any valid claim of the Borody patents.

Knowledge alone—especially when the knowledge is of a priority patent application—is insufficient. *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985); *Bayer Healthcare LLC v. Baxalta, Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021). Even Finch/UMN's own case, *C.R. Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1380 (Fed. Cir. 2020), required knowledge and evidence of intentional copying. Similarly, Finch/UMN's assertion that Rebiotix was interested in licensing the Borody patents but did not do so is unsupported. Dr. Borody, not Rebiotix, first reached out to collaborate, PTX-427, and although there were initial conversations about a collaboration, the talks did not proceed further, Tr. at 670:23-671:23. Thus, Finch/UMN point to no record evidence that Rebiotix believed it needed to take a license and the evidence from trial does not support such an inference.

Finally, Finch/UMN point to the merger agreement and the contemporaneous due diligence to assert that Ferring knew there was a risk it infringed the Borody patents based on Section 1.16(h). D.I. 514 at 26-27. Contrary to Finch/UMN's assertion, D.I. 514 at 27, the very documents Finch/UMN admitted into evidence provide evidence of the reason for the provision, *see, e.g.*, Tr. at 296:8-14. The jury is presumed to have considered all the evidence, *Power*

Integrations, Inc. v. Fairchild Semiconductor Int'l Inc., 935 F. Supp. 2d 747, 758 (D. Del. 2013), and here, the only reasonable conclusion is that Ferring believed it did not infringe. *See Bayer*, 989 F.3d at 987; *see also* PTX-56.0027, PTX-341.0004, TX-3960.0075, Tr. at 678:4-14.

Thus, even accepting Finch/UMN's evidence and drawing all inferences in Finch/UMN's favor, the evidence is insufficient to support a finding of willfulness. Knowledge of the patent applications (and later patents) and recognition of a potential future litigation risk is insufficient as a matter of law to support a finding of willfulness. *State Indus.*, 751 F.2d at 1236.

B. The UMN patent

Finch/UMN argue there is "no serious question" of willful infringement of the UMN patent based on the conclusory assertion that "Ferring [Pharma] and Rebiotix deliberately copied the UMN patent's disclosures to develop REBYOTA, without making any efforts to design around the claimed inventions." D.I. 514 at 27; *see also* D.I. 514 at 30. But Finch/UMN have not identified what novel information Ferring allegedly copied. First, Finch/UMN cite to Dr. Benson's testimony regarding inducement to support this assertion, D.I. 514 at 27, but this is not evidence of copying and cannot show Ferring's subjective belief of whether it infringed. *Bioverativ*, 2020 WL 1332921, at *4. It would have been clear error for any juror to consider this testimony for willfulness given that Dr. Benson testified that he was ***not*** at trial to talk about willfulness. Tr. at 381:7-13. At most, this evidence shows access.

Finch/UMN next argue that the jury's willfulness finding was justified based on copying because Ferring had access to UMN's confidential (and public) information, and because the process used to make REBYOTA is "substantially similar" to Hamilton 2012. D.I. 514 at 32. But Finch/UMN show no more than access. D.I. 514 at 28. And, as Finch/UMN later concede, access must be accompanied by "substantial similarity" to what is allegedly copied. D.I. 514 at 32; *see also Medtronic, Inc. v. Teleflex Innovations S.a.r.l.*, 70 F.4th 1331, 1340 (Fed. Cir. 2023)

(characterizing *Liqwd, Inc. v. L'Oreal USA, Inc*., 941 F.3d 1133, 1137 (Fed. Cir. 2019)); *Bayer*, 989 F.3d at 988; *BASF Plant Sci., LP v. CSIRO*, 28 F.4th 1247, 1274-75 (Fed. Cir. 2022). Finch/UMN's evidence fails to show substantial similarity. Finch/UMN argue that the REBYOTA process encompasses concepts disclosed in Hamilton 2012—"achieving a uniform suspension" with "the goal of cryopreserving the product." D.I. 514 at 32. It is undisputed that UMN did not invent mixing stool with saline to achieve a uniform mixture, *see, e.g.*, PTX-42.0013; Tr. at 121:18-23, and the use of cryoprotectants to preserve microbes during freezing has been known since the 1950's, Tr. at 144:19-21, 145:6-12. What the evidence showed is that Ferring developed its own product, which was the first FMT product to obtain FDA approval. If anything, that is evidence of obviousness, not copying. *Lindemann Maschinenfabrik GmbH v. Am. Hoist Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984).

Finally, Finch/UMN's reliance on the merger agreement and due diligence documents fails for the UMN patent for the same reasons discussed in Ferring's Opening Brief and above with respect to the Borody patents. Additionally, Finch/UMN now appear to concede that "the parent application had draft claim limitations that mirrored those that ultimately issued." D.I. 514 at 29. Ferring Pharma and Rebiotix specifically analyzed those "mirror" claims and believed they were not infringed and did so before the UMN patent issued and before this litigation.

VI. THE COURT SHOULD GRANT JMOL REGARDING DAMAGES

A. No reasonable jury could award an upfront payment

Mr. Malackowski failed to consider the value conferred by the novel aspects of the invention beyond that conferred by the conventional elements alone, and Mr. Malackowski failed to establish the Seres/Nestle agreement as a comparable license because he relied on only a loose, vague description of the covered technology and did not even know what intellectual property was licensed as part of that agreement. Because Mr. Malackowski's testimony is the

only basis on which the jury could have awarded an upfront payment, that portion of the damages award must be set aside. Moreover, Mr. Malackowski confused the jury regarding the nature of the Ironwood proposal and Seres/Nestle agreement by recognizing differences between product and patent licenses but treating both as straight patent licenses rather than product licenses—a position that Finch/UMN then doubled-down on in their post-trial briefing.

1. Mr. Malackowski did not consider "the value conferred by the conventional elements alone"

At trial, Finch/UMN contended that Hlavka was not invalidating prior art and decided not to have Mr. Malackowski separately consider the value of the invention described therein. But the jury disagreed and found claim 9 of the '080 patent and claim 21 of the '309 patent invalid over Hlavka, findings that Finch/UMN do not contest. With those decisions, there is no basis for Mr. Malackowski's opinions regarding apportionment because Mr. Malackowski admitted that he did "not stud[y] the value from the prior art of using a cryoprotectant," did "not stud[y] the value from the prior art of using an antioxidant," and "did not separately appraise the innovations in the Hlavka patents." Tr. at 514:17-515:7. To properly assess damages, "the question is how much new value is created by the novel combination, beyond the value conferred by the conventional elements alone." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015). Because Mr. Malackowski never considered "the value conferred by the conventional elements alone," he has no starting place and cannot have considered the incremental/new value added by the allegedly novel features and/or combinations of the Borody patents or UMN patent.

Finch/UMN's attempt to rely on the *Georgia-Pacific* factors as an end-run around this required analysis also is unavailing. Mr. Malackowski's failure to assess "the value conferred by the conventional elements alone" infects the entirety of his analysis, including his analysis of the individual *Georgia-Pacific* factors. This is highlighted by Finch/UMN's attempt to ignore

discrepancies between Mr. Malackowski's testimony and that of Dr. Benson regarding the importance of the patents. *See* D.I. 514 at 35 n.7. Mr. Malackowski provided his opinions based on the assumption that "in view of Finch's patent portfolio, it would be impossible to develop ***a product*** using fecal transplant technology directed to C. diff.," Tr. at 511:16-25, which Dr. Benson, in turn, denied, Tr. at 418:6-16. Similarly, the lack of non-infringing alternatives to REBYOTA is tied to issues concerning FDA approval, not technical feasibility. Tr. at 968:6-24.

2. Mr. Malackowski did not demonstrate that the Seres/Nestle agreement is a comparable license

Finch/UMN attempt to brush aside the fact that Mr. Malackowski did not know what patent rights were conveyed in the Seres/Nestle agreement, but that ignorance is fatal to his opinions regarding that agreement. Instead, Finch/UMN suggest that Mr. Malackowski showed technical comparability between the subject matter of the two licenses. D.I. 514 at 41. However, the entirety of this "analysis" was to rely on testimony from Dr. Benson that "even though the products are different, they're both FMT-type approaches, where fecal microbiota are being transferred and transplanted into individuals with recurrent CDI." Tr. at 401:25-402:5. But "[w]hen relying on licenses to prove a reasonable royalty, alleging a loose or vague comparability between different technologies or licenses does not suffice." *Laser-Dynamics, Inc. v. Quanta Computer, Inc*., 694 F.3d 51, 79 (Fed. Cir. 2012). That is because reasonable royalty opinions "relying on licenses must account for [ ] distinguishing facts when invoking them to value the patented invention." *Ericsson, Inc. v. D-Link Sys, Inc*., 773 F.3d 1201, 1227 (Fed. Cir. 2014). Therefore, "comparisons of past patent licenses to the infringement must account for the technological and economic differences between them." *Wordtech Sys., Inc. v. Integrated Networks Sol'ns, Inc*., 609 F.3d 1308, 1320 (Fed. Cir. 2010) (cleaned up).

3. Mr. Malackowski conflated product licenses with patent licenses

Ferring is not arguing that a product license *per se* cannot be used in the context of a damages analysis considering the results of a hypothetical negotiation. *Contra* D.I. 514 at 40. However, it is undisputed that both experts agree that "a product license is fundamentally different from a patent license." Tr. at 923:21-924:2, 520:10-14. Despite recognizing this distinction, Mr. Malackowski conflated the two types of agreements in presenting his opinions.

For example, Finch/UMN suggest that it "was not [Mr. Malackowski's] testimony" that "the entire $175 million upfront payment in the Seres agreement 'is attributable to intellectual property rights,'" D.I. 514 at 42, but the record directly contradicts this representation. Mr. Malackowski's only basis for the amount of an upfront payment was the Seres/Nestle agreement—in the first step of his attempt to apportion that agreement, he noted that it "was a license for intellectual property," which he testified "means patents and know-how," and that "there were documents that allowed [him] to understand that those are roughly of equal value, so [he] took the 175 million, [he] subtracted or apportioned out the know-how, and now [his] starting point is down to 87.5 million." Tr. at 503:15-504:6. Thus, Mr. Malackowski testified that the entire $175 million upfront payment was attributable to intellectual property (half to patents and half to know-how). Similarly, Finch/UMN contend that Mr. Malackowski did not use the upfront payment in the Ferring/Rebiotix Merger Agreement as a basis to apportion, D.I. 514 at 39, but his own testimony tells a different story, Tr. at 504:21-505:6.

Additionally, with respect to both the Seres/Nestle agreement and the Ironwood proposal, Finch/UMN admits that "Mr. Malackowski agreed that these licenses were not bare patent licenses, which the documentary evidence likewise confirms." D.I. 514 at 43. However, Finch/UMN do not address Mr. Malackowski's inconsistent representation of the Seres/Nestle agreement as "an IP license," *see* Tr. at 489:14-490:4, 490:14-491:1, or the Ironwood proposal as

an "offer[] to license [Finch's] patents" that "represents essentially a floor," *see* Tr. at 491:19-492:5. Mr. Malackowski's characterization of these licenses as something that they are not—bare patent licenses, which Mr. Malackowski recognized are fundamentally different than product licenses—created the confusion in this case. D.I. 502 at 39-42.

B. If not JMOL, the Court should remit the upfront payment to zero

Ferring's alternative argument for remittitur is not conclusory. Indeed, the same reasons supporting vacating the award support remittitur. And if Mr. Malackowski's improper opinions regarding the Seres/Nestle agreement are set aside, the record is wholly lacking in evidence to support a specific upfront payment. While Ferring believes this justifies vacating the award as a matter of law, to the extent the Court disagrees, the award still should be remitted to zero.

C. If the Court finds either the Borody patents or the UMN patent invalid or not infringed, then damages should be reduced

Finch/UMN's reliance on an out-of-district case to suggest that Ferring "forfeited" its argument that damages should be reduced if only the Borody patents or the UMN patent is valid and infringed makes little sense, particularly where, as here, the experts agree that reduction would be appropriate. Tr. at 506:10-507:1, 934:19-935:4. Finch/UMN's attempt to distinguish the cases cited by Ferring and reliance on *Hologic v. Minerva Surgical*, 957 F.3d 1256, 1271 (Fed. Cir. 2020) both rest on the assumption that the subject matter of the patents are coextensive, but that is not the case. For example, Finch/UMN's expert testified that if just the Borody patents were found valid and infringed, then damages should be reduced by 50% because all sales would infringe the Borody patents; but that if just the UMN patent is found valid and infringed, prior to reducing by 50% you also must "reduce the running sales by about 16% because the technical experts say they can only verify an 84.43% of the sales that they infringed that University claim." Tr. at 506:10-507:1. The rights conferred by the two sets of patents are not coextensive.

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